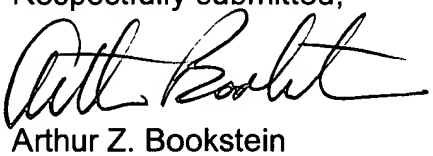
REMARKS

None of the foregoing amendments is considered or intended to narrow the scope of the claims and none has been made for purposes of patentability. The amendments have been made to conform to the claim numbering requirements. Amendments to the written description are intended only for reasons of syntax. Entry of the forgoing amendment is requested.

Respectfully submitted,



Arthur Z. Bookstein
Reg. No. 22,958
KIRKPATRICK & LOCKHART LLP
75 State Street
Boston, Massachusetts 02110
Tel: (617) 261-3100
Customer No.: 022832
Attorney for Applicants

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Version of Changes with Markings to Show Changes Made

Page 1, line 12

BACKGROUND [ART]

Page 1, lines 16, 19, 20

The Foley catheter is a catheter device usually made out of elastomeric material, which is for urine drainage and which is installed with its distal end in the bladder of the patient. When the distal end [reaches] of the catheter has been advanced into the bladder, sterile water is caused to flow along a lumen from the proximal to the distal end of the catheter, there to fill a balloon at the distal end of the catheter [surrounding the lumen and defined by the elastomeric wall of the catheter.] This balloon retains the distal end of the catheter in the bladder and allows a second lumen in the catheter shaft, open to the bladder at the distal end of the shaft, to drain urine from the bladder to the proximal end of the catheter.

Page 1, lines 25 and 26

In a [so-called] pre-filled Foley catheter, such as shown in U.S. Patent 3,602,226 the device includes [comes complete with] a reservoir of sterile water in the proximal

Page 2, lines 8-11

end of the device, and a clip over the shaft of the catheter at its proximal end, which clip prevents the sterile water from flowing from the distended reservoir bulb along the lumen to the distal end of the catheter. The person placing the catheter is required to hold the catheter in the desired disposition relative to the body of the patient, and then remove the clip and squeeze the reservoir bulb, in order to inflate the balloon. It would be desirable to provide an improved device for preventing fluid flow from the reservoir to the balloon until it is desired to do so. U.S. patents 3,75,001 and 3,675,658 disclosed the use of internal plugs instead of clip. [See US-A 3602226 for a disclosure of such an external valve. See US-A-3275001 and US-A-3675658 for disclosures of using a plug inside the lumen instead of an external clip.]

Page 2, line 22

Achievement of satisfactory shelf-life for pre-filled Foley catheters has proved to be a challenge. Common elastomeric material, such as latex, is not entirely impermeable to the passage of water. Accordingly, the water in the distended bulb reservoir of elastomeric material can escape through the wall, given enough time. In order to achieve a satisfactory shelf-life (18 to 24 months) it has been proposed to cover the outside of the reservoir bulb with a coating of material more resistant to passage of water than latex. Nevertheless, residual [problems remain. , For a discussion see US-A-3602226.] problems remain, some of which are discussed in the U.S. patent 3,602,226.

Page 3, insert after "SUMMARY OF THE INVENTION"

The invention may be incorporated in embodiments that may include one or more of the following objects, features and characteristics.

Page 4, lines 7 and 8

identified above, and which is characterized in that said control device comprises a plug which blocks the lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb to the [fluid acceptor] balloon to [fully] fill the balloon [acceptor].

Page 4, delete lines 9 and 10.

[By resorting to a plug with a parting line, a number of unforeseen advantages emerge, as follows.]

Page 4, line 11

Advantageously [Once] the plug is parted, there is no need for the person installing the catheter to manipulate any longer the plug or lumen

Page 4, line 14

Additionally [The] stress distribution in the wall of the bulb at the neck at its distal end is much more uniform with a plug than with the customary clip. An enhanced ability to predict patterns of stress and strain at the balloon neck should in turn allow better waterproofing in the distal neck region.

Page 4, line 19

Moreover, [Provision] of a parting line avoids the need to disturb the interface between plug and lumen. This is especially advantageous with latex lumens, or other lumens created by dipping, in which the wall thickness varies, because actuation of the control device need not involve any surface in contact with the lumen wall. Where the lumen wall thickness varies, so will the elastic performance, and when the elastic performance varies, there will be unpredictability in the manipulation of any surfaces constrained elastically by the lumen wall surface.

Page 5, line 2 and 3

Conventionally, a Foley catheter of latex is moulded with a narrow lumen of the order of [(say 0.8 mm diameter)] and a proximal bulb inner diameter much larger. Thus, [with] in another aspect of the invention, the distal neck of the bulb cavity can be molded to correspond in shape with the distal end of the plug. These complementary surfaces prevent excessive advance of the plug distally beyond the bulb neck.

Page 6, cancel lines 1-15 and substitute with the following:

[Prior to the making of this invention, applicant experimented with waterproof coatings on the inside of the elastomeric bulb. These attempts were abandoned because it was found that the material of the coating tended to block the lumen at the distal end of the bulb. However, with the present invention, there is fresh potential for waterproofing the inside of the bulb, because the placement of the plug in the distal neck of the bulb, before any fluid –impervious coating is introduced onto the inside surface of the bulb wall, will prevent the coating material from blocking the lumen at the

distal end of the bulb. With appropriate design of the plug, a coating of proofing material on the external surface of the plug ought not to have any adverse effect on the operation of the control device.]

In another aspect of the invention, the use of the plug facilitates avoidance of potential difficulties in coating the interior of the reservoir, as may be desired to waterproof the reservoir to minimize liquid loss during storage. By placement of a plug in the distal neck of the bulb, before the coating process the coating material will be precluded from blocking the lumen. A coating of proofing material on the external surface of the plug ought not to have any adverse effect on the operation of the plug device.

Page 7, line 16

In a [second] further aspect the present invention provides a medical device which is a drainage catheter having first and second lumens, with the first lumen serving as a drainage lumen and having a fluid inflow port at its distal end and a fluid drain coupling at its proximal end. The second lumen serves to convey inflating fluid from a fluid supply element at the proximal end of the device to a fluid acceptor balloon at the distal end. The fluid supply element and fluid drain coupling are arranged side by side at the proximal end of the coupling, and the device is characterized by a sleeve which extends around both the fluid drain coupling and the fluid supply element.

Page 17, lines 8 and 9

Although the presently preferred embodiment involves a circle of weakness, and parting of the polymer material around the weakness circle 31, nevertheless it is contemplated that alternative embodiments, may be desirable [not presently preferred, might in the end prove more attractive], in which, for example the stem portion 27 is not integral with the plug portion 26 but, rather, is a separate piece which is friction fitted with the proximal end 28 of the bore 29. If this were the case, then it might be appropriate to provide stepped or tapered portion of the proximal end of the bore 29 or the distal end of the stem 27.

Page 18, line 1

[Moving on to drawing] Figures 4 and 5, illustrate [here are shown] alternatives, in accordance with the second aspect of the present invention, to coating the fluid supply element at the proximal end of the device. Instead of dipping the proximal end in a coating liquid, the proximal end is surrounded by a sleeve. This sleeve can be like the sleeve 40 of Figure 4, embracing both the bulb 21 and the coupling element 15, or like the sleeve 42 of Figure 5, embracing only the bulb 21 and not the coupling 15.

Page 20, line 16

[Turning now to] Figure 6, [this] shows schematically the presently favoured method which applicant uses to insert the fluid control device 25 into the lumen of the catheter. A plurality of long flexible fingers 50, themselves mounted at their proximal ends to a finger ring 52, are introduced into the open end 22 of the catheter lumen which is to become the elastomeric bulb 21. Radially outward movement of the fingers 50 allows the plug 25 to be advanced axially past the open end 22 of the lumen, and beyond the part of the lumen 21 which becomes the bulb, until the plug 25 reaches the part 23 of the lumen which will become the distal neck of the bulb 21. Here, the lumen narrows down, over the length of a neck-in section R4 to the diameter of the lumen in the shaft, which here is 0.8 mm.

CLAIMS

Cancel claim 30.

Rewrite claims 6, 7, 12-14, 16, 18, 22-29 and 34-38 as follows:

6. Device as claimed in claim 1 [any one of the preceding claims], wherein the acceptor is a balloon (20).

7. Device as claimed in claim 1 [any one of the preceding claims] wherein the medical device is a catheter (10).

12. Device as claimed in claim 9 [any one of the preceding claims], wherein the acceptor (20) is made of elastomer.

13. Device as claimed in claim 9 [any one of the preceding claims] and made of latex rubber.

14. Device as claimed in claim 9 [any one of the preceding claims] wherein the fluid is a liquid, and the fluid supply element (21) contains said fluid.

16. Device as claimed in claim 1, [any one of the claims 1 to 8, 11, or any one of claims 12 to 15 as dependent on claim 11,] wherein the diameter of the annular part of the plug is at least three times that of the stem.

18. Device as claimed in claim either one of claims 16 or 17, wherein said stem (27) extends proximal of the annular port [part], coaxially therewith and has an outside diameter substantially less than that of said annular [part] port (26).

22. Device as claimed in claim 16 [any one of claims 16 to 21], wherein the axial length of the annular [part] port of the plug is greater than its largest diameter.

23. Device as claimed in either one of claims 1 or 16 [any one of the preceding claims,] wherein the length of the cylindrical portion is smaller than its radius.

24. Device as claimed in either [any] one of claims 1 or 16, [the preceding claims,] in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which is larger than the small end of the tapering portion.

25. Device as claimed in either [any] one of claims 1 or 16 [the preceding claims], in which the tapering portion comprises a frusto-conical of substantially frusto-conical portion which has a small end which constitutes the small

end of the tapering portion.

26. Device as claimed in claim 24 [claim 25, as dependent on claim 24] wherein the tapering portion comprises first and second frusto-conical or substantially frusto-conical portions, of different cone angle, such that the diameter of the tapering portion varies along the axis at a greater rate near the small end of the tapering portion than at the large end of the tapering portion.

27. Device as claimed in claim 1 [any one of the preceding claims] in which the stem is cylindrical.

28. Device as claimed in claim 1 [any of the preceding claims] wherein the fluid supply element (21) has an open proximal end (22) closed by a filler valve (24).

29. Device as claimed in claim 1 [any one of the preceding claims,] and which is a urinary drainage catheter.

34. Apparatus as claimed in claim 9[, or any one of claims 10 to 30 as dependent on claim 9,] wherein the sleeve is of shrink-wrap material.

35. Apparatus as claim in claim 1 [any one of claims 1 to 8] wherein the elastomeric bulb is sleeved in shrink-wrap material.

36. Apparatus as claimed in either one of claims 34 or 35 wherein the permeability of the sleeve material to diffusion of water therethrough is less than that of latex rubber.

37. Apparatus as claimed in either one of claims 34 or 35 wherein the shrink-wrap material is polystyrene.

38. Apparatus as claimed in either [any] one of claims 34 or 35 [to 37]

wherein the shrink-wrap sleeve incorporates a tear strip.

Version of Changes in Clean Form

Page 1, line 12

BACKGROUND

Page 1, line 16-19

The Foley catheter is a catheter device usually made out of elastomeric material, which is for urine drainage and which is installed with its distal end in the bladder of the patient. When the distal end of the catheter has been advanced into the bladder, sterile water is caused to flow along a lumen from the proximal to the distal end of the catheter, there to fill a balloon at the distal end of the catheter . This balloon retains the distal end of the catheter in the bladder and allows a second lumen in the catheter shaft, open to the bladder at the distal end of the shaft, to drain urine from the bladder to the proximal end of the catheter.

A1

Page 1, line 25 and 26

In a pre-filled Foley catheter, such as shown in U.S. Patent 3,602,226 the device includes a reservoir of sterile water in the proximal

Page 2, lines 8-11

end of the device, and a clip over the shaft of the catheter at its proximal end, which clip prevents the sterile water from flowing from the distended reservoir bulb along the lumen to the distal end of the catheter. The person placing the catheter is required to hold the catheter in the desired disposition relative to the body of the patient, and then remove the clip and squeeze the reservoir bulb, in order to inflate the balloon. It would be desirable to provide an improved device for preventing fluid flow from the reservoir to the balloon until it is desired to do so. U.S. patents 3,75,001 and 3,675,658 disclosed the use of internal plugs instead of clip.

A2

Page 2, line 22

Achievement of satisfactory shelf-life for pre-filled Foley catheters has proved to be a challenge. Common elastomeric material, such as latex, is not entirely impermeable to the passage of water. Accordingly, the water in the distended bulb reservoir of elastomeric material can escape through the wall, given enough time. In order to achieve a satisfactory shelf-life (18 to 24 months) it has been proposed to cover the outside of the reservoir bulb with a coating of material more resistant to passage of water than latex. Nevertheless, residual problems remain some of which are discussed in the U.S. patent 3,602,226.

Q3

Page 3, insert after "SUMMARY OF THE INVENTION"

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Page 4, lines 7 and 8

identified above, and which is characterized in that said control device comprises a plug which blocks the lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb to the balloon to fill the balloon.

Q5

Page 4, delete lines 9 and 10.

Page 4, line 11

Advantageously the plug is parted, there is no need for the person installing the catheter to manipulate any longer the plug or lumen

NC

Page 4, line 14

Additionally stress distribution in the wall of the bulb at the neck at its distal end is much more uniform with a plug than with the customary clip. An enhanced ability to predict patterns of stress and strain at the balloon neck should in turn allow better

waterproofing in the distal neck region.

Page 4, line 19

Moreover, of a parting line avoids the need to disturb the interface between plug and lumen. This is especially advantageous with latex lumens, or other lumens created by dipping, in which the wall thickness varies, because actuation of the control device need not involve any surface in contact with the lumen wall. Where the lumen wall thickness varies, so will the elastic performance, and when the elastic performance varies, there will be unpredictability in the manipulation of any surfaces constrained elastically by the lumen wall surface.

NE

Page 5, line 2 and 3

Conventionally, a Foley catheter of latex is moulded with a narrow lumen of the order of and a proximal bulb inner diameter much larger. Thus, in another aspect of the invention, the distal neck of the bulb cavity can be molded to correspond in shape with the distal end of the plug. These complementary surfaces prevent excessive advance of the plug distally beyond the bulb neck.

Page 6, cancel lines 1-15 and substitute with the following:

In another aspect of the invention, the use of the plug facilitates avoidance of potential difficulties in coating the interior of the reservoir, as may be desired to waterproof the reservoir to minimize liquid loss during storage. By placement of a plug in the distal neck of the bulb, before the coating process the coating material will be precluded from blocking the lumen. A coating of proofing material on the external surface of the plug ought not to have any adverse effect on the operation of the plug device.

Page 7, line 16

In a further aspect the present invention provides a medical device which is a drainage catheter having first and second lumens, with the first lumen serving as a

drainage lumen and having a fluid inflow port at its distal end and a fluid drain coupling at its proximal end. The second lumen serves to convey inflating fluid from a fluid supply element at the proximal end of the device to a fluid acceptor balloon at the distal end. The fluid supply element and fluid drain coupling are arranged side by side at the proximal end of the coupling, and the device is characterized by a sleeve which extends around both the fluid drain coupling and the fluid supply element.

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Although the presently preferred embodiment involves a circle of weakness, and parting of the polymer material around the weakness circle 31, nevertheless it is contemplated that alternative embodiments, may be desirable, in which, for example the stem portion 27 is not integral with the plug portion 26 but, rather, is a separate piece which is friction fitted with the proximal end 28 of the bore 29. If this were the case, then it might be appropriate to provide stepped or tapered portion of the proximal end of the bore 29 or the distal end of the stem 27.

NE

Page 18, line 1

Figures 4 and 5, illustrate alternatives, in accordance with the second aspect of the present invention, to coating the fluid supply element at the proximal end of the device. Instead of dipping the proximal end in a coating liquid, the proximal end is surrounded by a sleeve. This sleeve can be like the sleeve 40 of Figure 4, embracing both the bulb 21 and the coupling element 15, or like the sleeve 42 of Figure 5, embracing only the bulb 21 and not the coupling 15.

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lumen 21 which becomes the bulb, until the plug 25 reaches the part 23 of the lumen which will become the distal neck of the bulb 21. Here, the lumen narrows down, over the length of a neck-in section R4 to the diameter of the lumen in the shaft, which here is 0.8 mm.

CLAIMS

Cancel claim 30.

Rewrite claims 6, 7, 12-14, 16, 18, 22-29 and 34-38 as follows:

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13. Device as claimed in claim 9 and made of latex rubber.

14. Device as claimed in claim 9 wherein the fluid is a liquid, and the fluid supply element (21) contains said fluid.

16. Device as claimed in claim 1, wherein the diameter of the annular part of the plug is at least three times that of the stem.

18. Device as claimed in claim either one of claims 16 or 17, wherein said stem (27) extends proximal of the annular port, coaxially therewith and has an

outside diameter substantially less than that of said annular port (26).

22. Device as claimed in claim 16, wherein the axial length of the annular port of the plug is greater than its largest diameter.

23. Device as claimed in either one of claims 1 or 16 wherein the length of the cylindrical portion is smaller than its radius.

24. Device as claimed in either one of claims 1 or 16, in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which is larger than the small end of the tapering portion.

25. Device as claimed in either one of claims 1 or 16, in which the tapering portion comprises a frusto-conical of substantially frusto-conical portion which has a small end which constitutes the small end of the tapering portion.

26. Device as claimed in claim 24 wherein the tapering portion comprises first and second frusto-conical or substantially frusto-conical portions, of different cone angle, such that the diameter of the tapering portion varies along the axis at a greater rate near the small end of the tapering portion than at the large end of the tapering portion.

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dependent on claim 9,] wherein the sleeve is of shrink-wrap material.

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